

### REMARKS

Claims 1, 3-5 and 8 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Widlund et al.* (U.S. 4,222,381) in view of *Sheldon* (U.S. 4,650,459). Claims 6 and 7 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Widlund et al.* in view of *Sheldon*, as applied to claim 1 above, and further in view of *Buck et al.* (U.S. 5,725,481). These rejections are respectfully traversed on the grounds that these references are defective in establishing a *prima facie* case of obviousness.

There must be a basis, incentive, motivation in the art for combining the references.

Independent claims 1, 6 and 8 each include: ... a textured flexible mesh covering the absorbent member for: retaining the shape and limiting swelling of the absorbent member in response to the absorbent member becoming wetted by vaginal fluids; capturing cells residing in the vaginal fluids; and passing the cells to the absorbent member; and means for retrieving the absorbent member.

The final rejection based on *Widlund et al.* is clearly in error. Claims 1, 6 and 8 should have been allowed. However, the amendments to claims 1, 6 and 8 are made to further clarify the device. Allowance is requested.

The USPTO has taken the position that *Widlund et al.* includes a "(textured mesh) sheath 3 that is molded onto the absorbent member such that the sheath covers the absorbent member," and ..... "The sheath also retains the shape of the absorbent member," See Office Action at page 3.

This is an erroneous interpretation of *Widlund et al.* which clearly states at column 5, lines 23-25, the absorbent material remains unexpanded when dry but swells when wetted in the vagina.

It should be kept in mind that the *Widlund et al.* device is for swelling by absorbing vaginal fluids in order to block leakage of the fluids, i.e. a tampon. The Applicant's device is not a tampon for blocking such leakage but is for the purpose of collecting the vaginal fluids. Therefore, swelling of the absorbent member of the Applicant's device is restrained by the mesh, see the specification at paragraphs [0018] and [0019].

As the PTO recognizes in MPEP § 2142:

...The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the Examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness.....the Examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made....The Examiner must put aside knowledge of the Applicant's disclosure, refrain from using hindsight, and consider the subject matter claimed 'as a whole.'"

The Federal Circuit has, on many occasions, held that there was no basis for combining references to support a 35 U.S.C. §103 rejection. For example, in *In re Geiger*, the court stated in holding that the PTO "failed to establish a *prima facie* case of obviousness":

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. *ACS Hospital Systems, Inc. v. Monteffore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)

The Federal Circuit has also repeatedly warned against using the Applicant's disclosure as a blueprint to reconstruct the claimed invention out of isolated teachings in the prior art. See e.g., *Grain Processing Corp. v. American Maize-Products*, 840 F.2d 902, 907, 5 USPQ2d 1798, 1792 (Fed. Cir. 1989).

More recently, the Federal Circuit found motivation absent in *In re Rouffet*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998). In this case, the court concluded that the board had "reversibly erred in determining that one of [ordinary] skill in the art would have been motivated to combine these references in a manner that rendered the claimed invention [to have been] obvious." The court noted that to "prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the Examiner to show a motivation to combine the references that create the case of obviousness." The court further noted that there were three possible sources for such motivation, namely "(1) the nature of the problem to be solved; (2) the teachings of the prior art; and (3) the knowledge of persons of ordinary skill in the art." Here, according to the court, the board had relied simply upon "the high level of skill in the art to provide the necessary motivation," without explaining what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination. Notably, the court wrote: "If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technical advance."

Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection because none of the references teach or even suggest the desirability of the combination. Moreover, none of the references provide any incentive or motivation supporting the desirability of the combination.

The MPEP § 2143.01 provides:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Therefore, the Examiner's combination arises solely from hindsight based on the invention without any showing of suggestion, incentive or motivation in either reference of the combination.

All claim limitations must be considered.

As the PTO recognizes in MPEP §2142:

... The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the Examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness...

Thus, the rejection is improper because, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. In this context, 35 USC §103 provides that:

A patent may not be obtained...if the differences between the subject matter sought to be patented and the prior art are such that the *subject matter* as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains... (Emphasis added)

The Federal Circuit has held that a reference did not render the claimed combination *prima facie* obvious in *In re Fine*, 873 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), because inter alia, the Examiner ignored a material, claimed, temperature limitation which was absent from the reference. In variant form, the Federal Circuit held

in *In re Evanega*, 829 F.2d 1110, 4 USPQ2d 1249 (Fed. Cir. 1987), that there was want of *prima facie* obviousness in that:

The mere absence [from the reference] of an explicit requirement [of the claim] cannot reasonably be construed as an affirmative statement that [the requirement is in the reference].

In *Jones v. Hardy*, 727 F.2d 1524, 220 USPQ 1021 (Fed. Cir 1984), the Federal Circuit reversed a district court holding of invalidity of patents and held that:

The “difference” may have seemed slight (as has often been the case with some of history’s great inventions, e.g., the telephone) but it may also have been the key to success and advancement in the art resulting from the invention. Further, it is irrelevant in determining obviousness that all or all other aspects of the claim may have been well known in the art.

The Federal Circuit has also continually cautioned against myopic focus on the obviousness of the difference between the claimed invention and the prior art rather than on the obviousness vel non of the claimed invention as a whole relative to the prior art as §103 requires. See, e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc.* 802 F.2d 1367, 1383, 231 USPQ 81, 93 (Fed. Cir. 1986).

Because all the limitations of independent claims 1, 6 and 8 have not been met by the references, it is impossible to render the subject matter as a whole obvious. Thus, the explicit terms of the statutes have not been met and the Examiner has not borne the initial burden of factually supporting any *prima facie* conclusion of obviousness.


Therefore, independent claims 1, 6 and 8 and the claims dependent therefrom are submitted to be allowable.

PATENT

Docket Number: 30368.5  
Customer No. 000027685

In view of the above, it is respectfully submitted that remaining claims 1 and 3-8 are in condition for allowance. Accordingly, an early Notice of Allowance is courteously solicited.

Respectfully submitted,



James R. Bell  
Registration No. 26,528

Dated: 2-21-05  
HAYNES AND BOONE, L.L.P.  
901 Main Street, Suite 3100  
Dallas, Texas 75202-3789  
Telephone: 512/867-8407  
Facsimile: 214/200-0853  
ipdocketing@haynesboone.com

A-173943\_1.DOC

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop AF, Commissioner For Patents, Washington, D.C. 20231	
on	<u>2/21/05</u>
Date	<u>NPL</u>
Signature	<u>NISHI PASARNA</u>
Typed or Printed name of person signing Certificate	